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## PECB QMS ISO 9001:2015 Lead Auditor Exam Sample Questions (Q35-Q40):

### NEW QUESTION # 35

Select the term that best describes the purpose of retaining documented information in a quality management system to ISO 9001.

- A. To provide confidence in the effectiveness of the quality management system
- B. To safeguard the integrity of the quality management system
- C. To support the operation of the processes of the quality management system
- D. To facilitate auditing for proof of conformity to the standard.

**Answer: C**

Explanation:

Documented information is a means by which an organization demonstrates compliance. It communicates what we do and how we do things, it communicates what happened and what results were achieved. It is, essentially, a tool for communication. ISO 9001:2015 allows an organization flexibility in the way it chooses to document its quality management system (QMS). This enables each individual organization to determine the correct amount of documented information needed in order to demonstrate the effective planning, operation and control of its processes and the implementation and continual improvement of the effectiveness of its QMS. The standard states that the organization shall maintain documented information to the extent necessary to support the operation of processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned. Therefore, the purpose of retaining documented information is to support the operation of the processes of the QMS, not to facilitate auditing, provide confidence or safeguard integrity, which are secondary benefits of documented information.

References: Guidance on the requirements for Documented Information of ISO 9001:2015, ISO 9001:2015 documented information | CQI | IRCA, Documented Information Required by ISO 9001:2015 - 9000 Store

### NEW QUESTION # 36

Scenario 6: Davis Clinic (DC) is an American medical center focused on integrated health care. Since its establishment DC was committed to providing qualitative services for its clients, which is the reason why the company decided to implement a quality management system (QMS) based on ISO 9001. After a year of having an active QMS in place, DC applied for a certification audit.

A team of five auditors, from a well-known certification body, was selected to conduct the audit. Eva was appointed as the audit team leader. After three days of auditing, the team gathered to review and examine their findings. They also discussed the audit findings with DC's top management and then drafted the audit conclusions.

In the closing meeting, which was held between the audit team and the top management of DC. Eva presented two nonconformities that were detected during the audit. Eva stated that the company did not retain documented information regarding its outsourced services for an analysis laboratory and regarding the conducted management reviews. During the closing meeting, the audit team required from DC's top management to come up with corrective action plans within two weeks. Although the top management did not agree with the audit findings, the audit team insisted that the auditee must submit corrective actions within the given time frame in order for the audit activities to continue.

Once the action plans were evaluated, the audit team began preparing the audit report. Eva required from the team to provide accurate descriptions of the audit findings and the audit conclusions. The report was then distributed to all the interested parties involved in the audit, including the certification body. Based on the report, the certification body together with Eva, as the audit team leader, made the certification decision.

Based on the scenario above, answer the following question:

According to Scenario 6, the audit team required DC's top management to submit corrective action plans within two weeks. Is this action acceptable?

- A. Yes, because a deadline from 10 to 60 days is a best practice for the submission of action plans
- B. No, because the deadline for the client to present a corrective action plan is at least within 7 days
- C. No, because the decision for the deadline should have been suggested by the top management

**Answer: A**

Explanation:

Comprehensive and Detailed In-Depth Explanation: ISO 17021-1:2015, Clause 9.4.9 (Corrective Actions) states:

- \* The auditor can set a reasonable deadline for corrective actions.
- \* 10 to 60 days is a best practice timeframe for the auditee to respond.
- \* The auditee must propose corrective actions, but the audit team has the authority to set the deadline

A 7-day deadline (A) is too short, and the audit team-not the auditee-determines the timeframe (B).

### NEW QUESTION # 37

You are conducting an ISO 9001 audit of a Materials Recycling Facility. The organisation processes waste plastics into raw materials for plastic bottle manufacturers. You reach the manual picking line where operators are removing contaminant materials from incoming products, such as plastic bags, plastic film and badly contaminated items that would compromise the recycling process. You interview the line supervisor.

You: "Why are these plastic items being rejected at this stage?"

Auditee: "They do not meet our processing standards."

You: "What is the reason for that?"

Auditee: "These items are likely to damage the machinery down the line. They can also compromise our quality standards. We need to protect our reputation for good quality output materials." You: "What happens to the rejected items?" Auditee: "Some get melted down in another process later on, and some are disposed of as waste products that cannot be recycled." You: "What happens to the waste products?" Auditee: "I'm not sure. I suppose they go to landfill." After further auditing, you have gathered additional evidence. Match the following statements to the correct ISO 9001 standard clause shown.

To complete the table, click on the blank section you want to complete so that it is highlighted in red, and then click on the applicable text from the options below.

Alternatively, drag and drop each option to the appropriate blank section.

□

#### Answer:

Explanation:

□ Explanation:

A # 8.4.3.a

B # 7.2.b

C # 10.2.2

D # 10.2.1

E # 6.2

F # 5.2.2.c

\* 8.4.3.a - No specification is issued to the suppliers of waste plastic: This clause refers to the information provided to external providers, including requirements for products and services. If no specification is issued, it means the organization is not complying with this clause, which states:

"The organization shall ensure that the requirements for the products and services to be provided are adequately defined prior to communication to the external provider."

\* 7.2.b - The picking operators have been trained: This falls under Competence requirements. Clause

7.2(b) requires that persons are competent on the basis of education, training, or experience:

"Ensure that these persons are competent on the basis of appropriate education, training, or experience."

\* 10.2.2 - No documentation is retained for rejected materials: This relates to corrective action documentation. Clause 10.2.2 requires organizations to retain documented information as evidence of nonconformities and actions taken:

"The organization shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken..."

\* 10.2.1 - The rejected materials are segregated: This links to the treatment of nonconforming outputs. Clause 10.2.1 discusses actions such as containment or segregation for nonconforming outputs:

"Deal with nonconforming outputs in one or more of the following ways: correction; segregation, containment..."

\* 6.2 - Management has set an objective for the level of recycling: This refers to quality objectives.

Clause 6.2 requires that measurable quality objectives be established, and this includes setting performance targets:

"The organization shall establish quality objectives at relevant functions... The quality objectives shall be measurable..."

\* 5.2.2.c - The quality policy appears in promotional material: Clause 5.2.2(c) requires the quality policy to be available to relevant interested parties. Using it in promotional material ensures that it is communicated externally:

"The quality policy shall be... available to relevant interested parties, as appropriate." References:

ISO 9001:2015, Clause 8.4.3 - Information for external providers

Clause 7.2 - Competence

Clause 10.2.2 - Corrective action documentation

Clause 10.2.1 - Nonconforming outputs

Clause 6.2 - Quality objectives

Clause 5.2.2 - Communicating the quality policy

### NEW QUESTION # 38

How much time is usually spent on the Stage 1 audit?

- A. 30% of the total audit time
- B. 40% of the total audit time
- C. 20% of the total audit time

**Answer: A**

Explanation:

Comprehensive and Detailed In-Depth Explanation: According to ISO 17021-1:2015 (Conformity Assessment - Requirements for Certification Bodies), Clause 9.3.1.2, the Stage 1 Audit typically consumes around 30% of the total audit time.

This time is allocated to:

- \* Reviewing documented information.
- \* Assessing the readiness for Stage 2.
- \* Identifying potential nonconformities.

A 20% allocation (Answer A) is too low, and 40% (Answer C) is excessive, as the majority of the audit should be spent on Stage 2 (on-site verification).

### NEW QUESTION # 39

During a second-party audit of a dairy farm (by a potential customer) complying with ISO 9001:2015, the auditor verifies that there is large variability in the daily production of the milking yard. The current agreement with their only customer is to provide 2,000 litres per day. However, in the last two years, they have noticed an increasing variability in daily production.

If they produce less than 2,000 litres, they are penalised with a fine of 1.5 pesos for every litre that they do not provide. If they produce more than 2,000 litres, they use the extra milk to feed the pigs.

This process has been in operation for decades. The dairy farm was founded by the grandfather of the current owners, who did not want to alter the established practices.

The auditor raises a nonconformity on the basis that the process is not under control (Clause 8.1).

If you had been the auditor, which one of the following actions would you have accepted?

- A. Apply the existing process of addressing the risks and opportunities of milk production.
- B. Modify the contract with the current customer to provide them with only 1,500 litres of milk per day and make an agreement with a second customer.
- C. Retain the current contract and try to sell the occasional surplus milk to a second customer.
- D. Analyse the daily dispatch of milk for 7 days to determine its variability.

**Answer: A**

Explanation:

The action that the auditor would have accepted is:

\*Option B: Apply the existing process of addressing the risks and opportunities of milk production. This option is correct because ISO 9001:2015 clause 8.1 requires the organization to plan, implement and control the processes needed to meet the requirements for the provision of products and services, and to implement actions determined in clause 6.1, which refers to the actions to address risks and opportunities. The organization should apply the existing process of addressing the risks and opportunities of milk production, which may include identifying the sources of variability, assessing the potential impacts and consequences, determining and implementing appropriate actions to reduce or eliminate the variability, monitoring and measuring the effectiveness of the actions, and reviewing and updating the actions as necessary.

The following options are not correct:

\*Option A: Modify the contract with the current customer to provide them with only 1,500 litres of milk per day and make an agreement with a second customer. This option is not correct because it does not address the root cause of the variability in the daily production of the milking yard, which may affect the quality and consistency of the products and services provided by the organization. It also does not demonstrate the organization's commitment to meet the customer and applicable statutory and regulatory requirements, as required by ISO 9001:2015 clause 8.2.2.

\*Option C: Retain the current contract and try to sell the occasional surplus milk to a second customer. This option is not correct because it does not address the root cause of the variability in the daily production of the milking yard, which may affect the quality and consistency of the products and services provided by the organization. It also does not demonstrate the organization's

commitment to meet the customer and applicable statutory and regulatory requirements, as required by ISO 9001:2015 clause 8.2.2.

\*Option D: Analyse the daily dispatch of milk for 7 days to determine its variability. This option is not correct because it does not address the root cause of the variability in the daily production of the milking yard, which may affect the quality and consistency of the products and services provided by the organization. It also does not demonstrate the organization's commitment to implement actions to address risks and opportunities, as required by ISO 9001:2015 clause 8.1.

References:

\*ISO 9001:2015 Quality management systems - Requirements, Clause 8: Operation, Subclause 8.1:

Operational planning and control, Subclause 8.2: Requirements for products and services

\*ISO 9001 Lead Auditor Course Material, Module 4: ISO 9001:2015 Requirements, Slide 23: Clause 8 - Operation

\*ISO 9001 Lead Auditor Training Course - IRCA Certified, Section 4.2: ISO 9001:2015 Requirements, Subsection 4.2.8: Clause 8 - Operation

\*Lead Auditor Exam Preparation Guide (EPG) Template - PECB, Section 3.2: Exam Content Outline, Subsection 3.2.1: Section 1 - Audit Fundamentals, Subsection 3.2.2: Section 2 - Audit Principles, Subsection

3.2.3: Section 3 - Audit Process, Subsection 3.2.4: Section 4 - Audit Competencies

## NEW QUESTION # 40

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